



NDA 18-086/S-056

Merck & Co., Inc.  
Attention: Virginia G. Snyder  
Manager, Regulatory Affairs  
P.O. Box 4, BLA-20  
West Point, PA 19486

Dear Ms. Snyder:

Please refer to your supplemental new drug application dated May 31, 2001, received June 04, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Timoptic (timolol maleate ophthalmic solution) Sterile Ophthalmic Solution, 0.25% and 0.5%.

We acknowledge receipt of your submissions dated May 31 and June 6, 2001.

We note that this supplement was submitted as a 'Special Supplement – Changes Being Effected' under 21 CFR 314.70(c).

This supplemental new drug application provides for the addition of "anaphylaxis" to the **Adverse Reactions**, *Hypersensitivity* sub-section of the package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted May 31, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Michael Puglisi, Project Manager, at (301) 827-2090.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, M.D.  
Deputy Director  
Division of Anti-Inflammatory, Analgesic and Ophthalmic  
Drug Products, HFD-550  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

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/s/

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Wiley Chambers

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